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11 April 2000

Christine J. Lewis, Ph.D.
Dockets Management Branch (HFA-305)
Food and Drug Administration, Room 1061
5630 Fishers Lane
Rockville, MD 20852

RE: Docket #00N-0598, Federal Register 21 CFR Part 101

Dear Dr. Lewis:

I was disappointed to learn that the U.S. Court of Appeals in the District of Columbia reversed the lower court's decision regarding the authorization of health claims for specific substance/disease relationships as challenged in *Pearson vs. Shalala*. I believe this places the FDA in a untenable position in trying to authorize health claims for dietary supplements. At the present time, it is extremely difficult to determine from the scientific data available whether a specific health claim is not misleading consumers. If the FDA is placed in the position of regulating health claims for dietary supplements for the protection and promotion of public health, it would appear that significant resources need to be placed in their hands in order to conduct the appropriate studies to determine whether the claims are indeed tenable. Therefore, I recommend that establishing a standard, more rigorous and significant scientific agreement is the best way to distinguish amongst claims supported by different levels of evidence. This may mean the consideration of certain dietary supplements as drugs and to be regulated and studied for their efficacy following the accepted procedure for new drug approvals. Since much of the impetus for approval of a health claim is based on the ultimate marketing of a successful product, it is unclear whether the best interest of the public is taken into account once such an application or petition is submitted. Claims about the effects of dietary supplements on existing diseases are best authorized after significant basic research has been done regarding the mechanisms of action and the interactions of the constituents of the dietary supplements on various pathways. The dietary ingredients believed to be the active component of the dietary supplement needs to be identified and there should be in place a means of assessing the content of each nutraceutical of the active ingredient. The practice of medicine is becoming complicated by the number of over-the-counter supplements which interact with known pharmacologic treatments for known diseases. Oftentimes the public will not report the use of these supplements to their physician leading to sometimes untoward effects. In order to minimize these and to not use the public as the broad laboratory testing ground for diet-drug interactions, I would recommend that the FDA be authorized to review health claims as a drug.

Thank you for your consideration of my opinions and please feel free to contact me if you have any questions or need further clarification.

Yours sincerely,

Naomi K. Fukagawa, M.D., Ph.D.

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